



CARLISLE
DIGESTIVE
DISEASE
ASSOCIATES, Ltd.

GREGORY LEWIS, M.D., F.A.C.P.
THEODORE BERK, M.D., F.A.C.P.
ROBERT B. LEVY, D.O.
Board Certified in Gastroenterology

November 21, 2000

Food & Drug Administration
(HFI-35) 5600 Fishers Lane
Rockville, MD 20857

TO WHOM IT MAY CONCERN,

I am a practicing gastroenterologist for over 20 years and I wanted to write you a letter to give you my feeling on the current controversy involving the medication Lotronex which is used for irritable bowel symptoms in women.

I have been using this medication since it came onto the market and I find it to be very effective in controlling the diarrhea component of irritable bowel for women. I have not seen any side effects from it of a serious nature, only mild constipation that's easily treated. During my 20 years of practice, I have seen numerous women develop ischemic colitis. They are usually between the ages of 35-50. The ischemic colitis is mild and self-limiting and presents with crampy abdominal pain and bloody diarrhea. The preponderance of patients who develop ischemic colitis are females. Thus, I find interesting the reports that Lotronex is supposed to cause rare ischemic colitis since I feel if one carefully examines the issue that it is the same population that develops ischemic colitis without Lotronex. Since Lotronex came on the market, I have seen it used by physicians, perhaps incorrectly, using it in elderly people, occasionally using it in men and occasionally using it for patients with unexplained diarrhea. However, it's my strong opinion that it's an extremely efficacious drug with a very high safety profile and that the increased reports of side effects, when carefully examined, are related to the normal incidence of ischemic colitis in women and not related to the drug Lotronex. I feel that if it is used for women with irritable bowel and diarrhea that it should remain safe and I urge you to continue to allow it to be used.

Sincerely,


Gregory Lewis, M.D.

GL/rg

00P-1499

C24